REMARKS:

Claims 4, 9 and 14 have been amended to correct minor typographical errors. No new matter has been added.

Claims 1-4, 6-9 and 11-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,413,550 to Castel (the "Castel reference"), in view of Watkin, N.A. et al., "High-Intensity Focused Ultrasound Ablation of the Kidney in a Large Animal Model," Journal of Endourology, vol. 11, no. 3 (June 1997) (the "Watkin reference"), Hill, C.R. et al., "Lesion Development In Focused Ultrasound Surgery: A General Model," Ultrasound in Med. & Biol., vol. 20, no. 3, pp. 259-269 (1994) (the "Hill reference") and Billard, B.E. et al., "Effects of Physical Parameters on High Temperature Ultrasound Hyperthermia," Ultrasound in Med. & Biol., vol. 16, no. 4, pp. 409-420 (1990) (the "Billard reference"). The rejections are respectfully traversed.

The Castel reference discloses an ultrasound therapy system that includes an ultrasound transducer and a controller programmed to calculate ultrasound dosage, intensity and treatment time. (Castel, abstract.) However, the Examiner has conceded that the Castel reference does not disclose:

> determining an in vivo treatment time (or ultrasound acoustic power) from a function of experimentally determined in vitro treatment time (or ultrasound acoustic power) for the transducer to deliver ultrasound at the ultrasound acoustic power (or for the treatment time) for the in vitro treatment time (or at the in vitro ultrasound acoustic power) to thermally ablate patient tissue in vitro

or

> that the mathematical function includes blood perfusion rate and patient tissue density.

(Office action, p. 3.)

Thus, the Castel reference is of little relevance to the patentability of the claims of the present patent application.

The Watkin reference discloses using in vitro data to determine the relationship between ultrasound intensity and exposure time required to produce a thermal lesion. (Watkin, p. 194; *see also* Fig. 2.) The Watkin reference also discloses that "thermal lesion formation is

independent of organ perfusion for exposure times of approximately 3 second or less." (Watkin, p. 194.) Therefore, the Watkin reference concludes that short exposure times should be used such that in vitro data can be applied to in vivo procedures. (Watkin, p. 195.)

Thus, the Watkin reference discloses using short exposure times such that the practitioner can assume that in vivo treatment time equals in vitro treatment time. As such, the simplistic approach taught by the Watkin reference teaches away from calculating in vivo treatment time from a mathematical function of in vitro treatment time, blood perfusion rate and patient tissue density, as required by the claims of the present patent application.

The Hill reference discloses, as noted by the Examiner, "theoretical models of the formation of ultrasonic focal lesions in tissue." (Office action, p. 3; Hill, p. 260.) Furthermore, as noted by the Examiner, the Hill models include density and blood perfusion components, among other things. (Office action, p. 4; Hill, p. 260.) However, the Hill reference does not disclose models that correlate in vivo treatment time to in vitro treatment time or in vivo ultrasound acoustic power to in vitro ultrasound acoustic power.

Thus, the Hill reference is of no relevance whatsoever to the patentability of the claims of the present patent application.

Finally, the Billard reference discloses that short pulse lengths (2 seconds or less) and small focal diameters yield temperature elevations that "are nearly perfusion independent." (Billard, abstract.) Therefore, like the Watkin reference, the Billard reference encourages the use of short exposures times such that the perfusion rate need not be taken into consideration.

Accordingly, taken as a whole, the Castel, Watkin, Hill and Billard references suggest to their readers that ultrasonic therapy systems should employ short exposure times such that perfusion rates in vivo can be ignored.

Applicants have proceeded in a different direction. The claims of the present patent application do not ignore perfusion rate, but rather use profusion rate, among other parameters including tissue density and in vitro data, to mathematically derive an in vivo treatment time (or in vivo ultrasound acoustic power) that is typically different, and presumably more accurate, than the in vitro treatment time (or in vitro ultrasound acoustic power).

The Examiner's argument that the "prior work in correlating in vitro to in vivo ablation and the effects of both blood perfusion rates and tissue properties would be well known to one of

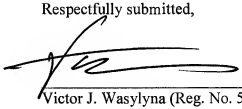
skill in the art" is without merit. First, the prior work in "correlating" in vitro to in vivo ablation simply relied upon a direct relationship: in vivo equals in vitro. (*See* Watkin.) The prior art of record does not disclose correlating in vitro to in vivo ablation using a mathematical relationship as Applicants have done and claimed. Second, the prior work regarding blood perfusion rates and tissue properties (e.g., the Hill reference) was not directed to, and did not result in, the correlations of in vitro to in vivo ablation that were discovered by Applicants. Therefore, the Examiner's argument in support of obviousness must fail.

Furthermore, the Examiner's argument that "the migration of an experimental laboratory procedure to a practical in vivo procedure is the cornerstone for most medical advances" is misplaced. Applicants did not migrate procedures. Rather, Applicants developed a system and method that combines both experimental and in vivo data to yield a useful result not previously disclosed or suggested in the prior art of record.

For the foregoing reasons, the Castel, Watkin, Hill and Billard references, whether taken alone or in combination, fail to disclose a controller that determines in vivo treatment times (or in vivo ultrasound acoustic power) from a mathematical function of experimentally-determined in vitro treatment time (or in vitro ultrasound acoustic power), blood perfusion rate and patient tissue density. As such, the asserted combination of references fails to teach each and every limitation of the pending claims and, therefore, fails to establish a proper prima facie case of obviousness.

Accordingly, the present patent application is in condition for allowance and formal notice thereof is respectfully requested.

Respectfully submitted,



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